

## REMARKS

Support for the amendment to claim 1 to recite that the compound is free from cotton seed tissue is found at page 2 line 19 of the specification. The "use" claims have been amended into conventional method of treatment claims and new claims 14 and 15 relating to diseases or conditions and new claims relating to the conditions specified in original claims 6 and 7 have been added dependent on claim 10. The various adjuvants previously indicated as being "included" in the composition of claim 8 have been made the features of specific sub claims 12, 16, 17 and 18. The abbreviation "etc" has been deleted.

The rejection under 35 USC 112 is respectfully traversed. The data set out in the present application show the activation effect of a compound of the present invention on adenylate cyclase in rat cerebral cortex tissue (Table 4), the protection effect of such a compound on PC-12 cells damaged by corticosterone (Table 5), the ability of the compound to reduce the period of immobility of mice in forced swimming tests (Tables 6 and 7) and the effects of the compound in a 5HT<sub>1A</sub> receptor test (Example 3.4).

It is submitted that protection of PC-12 cells from damage should be accepted by one skilled in the art as being indicative of utility in delay of senility, improvement of learning and memory in addition to the protection of cell from damage which is clearly demonstrated.

So far as treatment of depression, Alzheimer's disease, drug and alcohol disorders and panic states are concerned, it is submitted that one skilled in the art will recognize that the activation effect on adenylate cyclase in rat cerebral cortex tissue, the ability of the compound to reduce the period of immobility of mice in forced swimming tests, and the effects of the compound in a 5HT<sub>1A</sub> receptor test are all indicative of utility in treatment of the conditions in question. Enclosed herewith are copies of articles by Duman et al Biol Psychiatry (1999)46:1181-1191, Miro et al., Neuropharmacology 43 (2002) 1148 - 1157 and Griebel et al

Neuropharmacology 39 (2000) 1848 - 1857 which show the relevance of the first of these tests in treatment of depression (the Duman article) and Alzheimer's disease (the Miro article) and of the 5HT<sub>1A</sub> test on the treatment of anxiety (the Griebel article).

The amendment to claims 1 - 4 removes the basis for rejection of them under 35 USC 101. The claims now recite compounds when free from the materials with which some of them are found in nature. As noted in *Parke-Davis v. H. K. Mulford* 189 F 95 (S.D. NY 1911) aff'd 196 F 496 (2d Cir, 1912) where the claim was to adrenaline in a stable and concentrate form and practically free from inert and associated gland tissue

... even if it were an extracted product without change, there is no rule that such products are not patentable. Takamine was the first to make it available for any use by removing it from the other gland tissue with which it was found, and, while it is of course possible logically to call this a purification of the principle, it became for every practical purpose a new thing commercially and therapeutically. That was a good ground for a patent.

The same rationale applies here.

Furthermore, as now defined, claims 1 - 4 are novel since they no longer cover compounds in their natural state as discussed in the application. The rejection under 35 USC 102 over the acknowledgment in the specification should therefore be withdrawn.

Turning now to the rejection under 35 USC 102(a) over the Chinese Patent, it is pointed out that this was not published until March 28, 2001. The present application is entitled to a priority date of March 26, 2001, the filing date of application Serial No 60/278841. An English language text of that application was filed on January 26, 2004. The texts of the Chinese publication and the US provisional appear to be the same. The Chinese patent is therefore not a proper reference for citation against the present application since anything it discloses was included in the U.S. provisional which is of earlier date.

So far as the Li et al article is concerned, this was published in April 2000, that is less than one year prior to the filing of Serial No 60/278841. It is therefore not a proper reference under 35 USC 102(b). So far as its potential relevance under 35 USC 102(a) is concerned, five of the authors of the publication are the inventors named in the present application. The sixth named author was an assistant. Submitted herewith are declarations by the five inventors averring that they were the inventors of the claimed subject matter and that the sixth named author derived information from them thereby showing that the their invention of the claimed subject matter was prior to the publication of the Li et al paper.

In view of the fact that neither reference cited under 35 USC 102 is properly cited for the reason set out above, such references are not 'prior art' for the purposes of 35 USC 103 and the rejection under 35 USC 103 should therefore be withdrawn.

Applicant submits that the present application is in condition for allowance and favorable consideration is respectfully requested.

Respectfully submitted



John Richards  
c/o Ladas & Parry  
26 West 61st Street  
New York, New York 10023  
Reg. No. 31, 053 (212-708-1915)